DETAILED ACTION

Response to Amendment

The Information Disclosure Statement (IDS) filed 11 November 2009 has been entered. Applicant's amendment of the claims filed 11 November 2009 has been entered.

Claims 2-5, 7, 8, 11-16 and 19-23 are cancelled. Claim 30 have been added. Claims 1, 6, 9, 10, 17, 18 and 24-30 are pending. Claims 17 and 18 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention.

Examiner's Amendment

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in telephone interviews with attorney David Kurlansky on 11 February 2010.

Please amend the claims as the following:

1. A method of treating osteoarthritis in a human in need thereof comprising orally administering to said human a pharmaceutical composition comprising salmon calcitonin in free or salt form and a delivery agent selected from the group consisting of N-(5-chlorosalicyloyl)-8-aminocaprylic acid (5-CNAC), N-(10-[2-hydroxybenzoyl]amino)decanoic acid (SNAD), N-(8-[2-hydroxybenzoyl]amino)caprylic acid (SNAC), and disodium salts thereof, wherein

the amount of said salmon calcitonin in said pharmaceutical composition is between 0.4 and 1.2 mg.

6. The method according to claim 1, wherein the pharmaceutical composition further comprises at least one pharmaceutically acceptable pH-lowering agent, at least one absorption enhancer, and an enteric coating.

24. The method according to claim 1, wherein the amount of said salmon calcitonin in said pharmaceutical composition is between 0.8 and 1.2 mg.

26. The method according to claim 25, wherein the delivery agent is a disodium salt of 5-CNAC.

27. The method according to claim 24, wherein the amount of said salmon calcitonin in said pharmaceutical composition is about 1 mg.

30. A method of preserving and stimulating cartilage in a human having osteoarthritis comprising orally administering to said human a pharmaceutical composition comprising salmon calcitonin in free or salt form and a delivery agent selected from the group consisting of 5-CNAC, SNAD, SNAC, and disodium salts thereof, wherein the amount of said salmon calcitonin in said pharmaceutical composition is between 0.4 and 1.2 mg.

Please cancel claims 17 and 18.

The following is an examiner's statement of reasons for allowance: the amendment to the claims was made to clarify the claimed invention; in particular, to clarify that the amount of salmon calcitonin is between 0.4 and 1.2 mg (or is between 0.8 and 1.2 mg, or is about 1 mg), rather than "comprises" the recited amounts. The amendment to the claims with the recited amounts of salmon calcitonin would be commensurate in scope with the unexpected results as shown in the specification and Applicant's arguments. Applicant's response filed 11 November 2009 overcame all

remaining grounds of rejections and objections. Claims 17 and 18 are cancelled without prejudice to Applicant's intention to pursue the subject matter therein in continuing applications in the telephonic interview with the attorney on 11 February 2010.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Xiaozhen Xie, Ph.D whose telephone number is 571-272-5569. The examiner can normally be reached on M-F, 8:30-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary B. Nickol, Ph.D. can be reached on 571-272-0835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Xiaozhen Xie, Ph.D.
February 10, 2010

/Elizabeth C. Kemmerer/
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